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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/110,376	05/12/98	COHEN	S

THE LAW OFFICE OF JAMES C SIMMONS
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HM12/0828

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

19

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/110,376

Applicant(s)

Cohen et al

Examiner

Karen Canella

Art Unit

1642



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1835 C.D. 11; 453 O.G. 213.

4) Claim(s) _____ is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

Art Unit: 1642

Response to Arguments

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claim 1 is pending and under consideration.

New Grounds of Rejection

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "low metastatic potential" without a qualification of the term low. Amendment of the claim to recite "absence of lymph node metastases at the time of sampling" is recommended.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for predicting the absence of lymphotrophic metastatic potential of breast and colon tumors, does not reasonably provide enablement for predicting the absence of lymphotrophic metastatic potential of prostate tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claim 1 is drawn in part to a method of predicting the lymphotrophic metastatic potential of solid non-lymphoid primary tumors by assaying for the CD3 antigen, wherein lack of expression of this antigen is correlated with lack of metastatic potential and lack of metastatic events having occurred from said primary tumor.

Grignon et al (Journal of Urology, 1987, Vol. 137, pp. 330-332) disclose that an anti leu-4 antibody binds to normal, hyperplastic and metastatic prostate carcinoma. As leu-4 is a common synonym for CD3, Grignon et al teach away from the correlation between lack of expression of CD3 on a tumor tissue and lack of lymphotrophic metastasis, as normal and hyperplastic prostate tissue reacts with an anti-CD3 antibody. One of skill in the art would be subject to undue

Art Unit: 1642

experimentation without reasonable expectation of success in order to use the claimed method for predicting lack of lymph node metastasis in tumor tissues beyond breast and colon, as the data taught by Grignon et al, teaches against using the claimed method for predicting lymph node metastasis in prostate cancer by measurement of the CD3 antigen, and thus calls into question the scope of the claimed method.

5. All other rejections and objections as stated in Paper No. 14 are withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642

August 12, 2001

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